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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,197	09/21/2005	Young-Tack Sul	P57672	7327
7590	04/10/2007		EXAMINER	
Robert E Bushnell Attorney at Law Suite 300 1522 K Street NW Washington, DC 20005-1202			WERNER, JONATHAN S	
			ART UNIT	PAPER NUMBER
			3732	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/550,197	SUL, YOUNG-TAEK
	Examiner	Art Unit
	Jonathan Werner	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 January 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 September 2005 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/4/07</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to Applicant's amendment received on 1/4/07.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 1/4/07 is noted. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

3. Figures 6-8 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because Applicant recites that "micro-patterns preferably have a cross sectional area of 150 μm ." However, Examiner

notes that micrometers is not a proper unit of measure for designating area. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has added new limitations to claims 7 and 13 directed to "inclined flanks of said threads." For the purpose of examination, as best understood based on Applicant's original specification, Examiner will interpret said "flanks" to be the same as the "thread inclines" of claim 1.

6. Additionally, claims 12 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each claim recites "micro-patterns having cross sectional areas on an order of 150 μm ." However, Examiner notes that micrometers is not a proper unit of measure for designating area.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Dicke (US 5,044,853). As to claims 1 and 3, Dicke discloses a helically threaded screw with a core (Figures 1-3), with each of the threads having thread inclines comprising one or more recesses (13) and protrusions (12) as shown in Figure 2. As to claim 2, the recesses shown in Figures 2 and 3 have a polygonal cross-section opened at one side thereof.

8. Claims 7-10 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansson et al. (US 5,588,838). As to claims 7 and 13, Hansson discloses a helical implant with a core surrounded by helical threads (i.e. Figure 3), wherein the threads have continuous micro-patterns (i.e. 109) which increase the exposed surface of the implant. As to claims 8 and 14, the micro-patterns disclosed by Hansson can either be bead-shaped or thread-shaped (column 2, lines 28-30), both of which have polygonal cross-sections. In regard to claims 9 and 15, the micro-bead and micro-thread patterns described by Hansson comprise recesses and protrusions along the helical thread further characterized by the spaces between them (i.e. column 2, lines 62-63). As to

claims 10 and 16, the micro-beads are bead-shaped and thus also display arcuate cross sections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dicke in view of Hansson et al. (US 5,938,444). Dicke discloses the helical screw as described above but fails to show both the recesses and protrusions shown have an arcuate cross section of identical curvature and length. Hansson, however, teaches a helically threaded implant which has threads that form recesses and protrusions that have an arcuate cross section of identical curvature and length (Figure 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make the recesses and protrusions of the present invention have arcuate cross sections of identical curvature and length in order to avoid, or at least minimize, stress-concentrations in the bone tissue around the threads as taught by Hansson (column 2, lines 60-63). As to claims 5 and 6, Hanson further discloses the use of micro-threads that have dimensions in the micrometer range (column 2, lines 24-28) in order for the threads to function as a screw, though not specifically a cross sectional

area of $150 \mu\text{m}^2$. However, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make the implant with the recesses having such a cross sectional area since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Claims 11-12 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansson et al. (US 5,588,838). Hansson discloses the helical implant as previously described above, but fails to specifically disclose a cross sectional area of $150 \mu\text{m}^2$ or that the separation distance between adjacent recesses is $150 \mu\text{m}$. However, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make the implant with the recesses having such a cross sectional area and separation distance since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

11. Applicant's arguments filed 1/4/07 with respect to claims 1-6 have been fully considered but they are not persuasive. In response to applicant's argument that the intended use of the Dicke '853 reference is different than that of the present application, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Examiner further notes that the recesses and protrusions of the Dicke '853 reference, as described above, also increase the contact area between the screw and the site of implantation.

12. Applicant also remarks that in the present application, "the micro-patterns can be grooved not only close to the thread tip of the thread inclines, but also on the entire thread inclines, as shown in Figures 1 through 4." However, Examiner notes that such a distinction was never claimed. Additionally, Applicant states that the patterns on the threads as shown by Dicke '853 are smooth in contrast to that of the present application. But Examiner points out that Applicant contradictorily states in regard to claims 1, 7, and 13, that "the micro-patterns that are grooved on the thread inclines ... may be smooth ... or have edges." Consequently, the arcuate pattern shown by Applicant in Figure 3 does appear to have smooth edges.

13. With respect to Applicant's assertion that Dicke '853 only discloses recesses and protrusions on the thread tip instead of the thread incline, Examiner sustains that since the entirety of each thread is inclined, any placement of such recesses and protrusions along said thread would also be located on an inclined portion of said thread. Applicant even states, "the recesses and protrusions can be formed either on the entire thread inclines, or close to the thread tip."

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14. Furthermore, Examiner respectfully disagrees with Applicant's assertion that a polygon is strictly defined as a "closed plane figure bounded by straight lines." In fact, according to the Merriam-Webster dictionary, a polygon is also defined as "a closed figure on a sphere bounded by arcs of great circles." This understanding of a polygonal pattern clearly conforms to the patterns displayed in Dicke '853. Applicant has not claimed any further structural details other than the generic form of a polygon.

15. Lastly, in regard to claims rejected in view of Hansson '444, Applicant asserts that there is no teaching or suggestion by Hansson that micro-patterns can be formed in the thread inclines of the micro-thread, formed on the envelope surface of the body. However, as noted by Examiner above and further reiterated herein, Applicant never originally claimed such limitations related to "micro-patterns" or "micro-thread" formations.

Conclusion

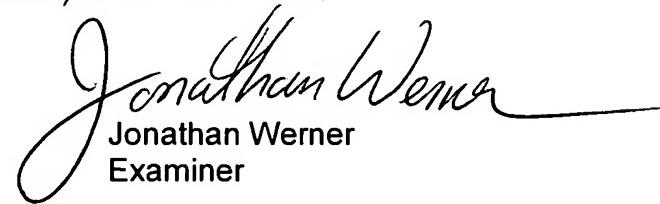
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then

the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jonathan Werner
Examiner

3/22/07


MELBA N. BUMGARNER
PRIMARY EXAMINER